JULY 13, 2003

VERIFYING EFFECTIVE OVERSIGHT OF YOUR HUMAN RESEARCH PROTECTION PROGRAM (HRPP): A CHECKLIST

1. Federalwide Assurance (FWA)

- ❑ Review your FWA
- ❑ Review the OHRP Terms of Assurance
- ❑ Is your institution in compliance with your commitment?
- ❑ Is your FWA current? If changes are necessary, make them now
- ❑ Report changes, if required, to the Office of Research Oversight (ORO, 10R) and OHRP
- ❑ Do those involved with your human research protection program understand their responsibilities under the FWA?

2. Building Blocks

- ❑ Are the staff and resources allocated to your research program sufficient to ensure the protection of human subjects?
- ❑ Has everyone involved in human research had training in human research protection and good clinical practices?

3. Nuts & Bolts

- ❑ Do you have a procedure for reviewing your human research protection program?
- ❑ Does the current membership of your **R&D Committee** meet the following regulatory guidelines?

Membership Criteria	**Name of person(s) filling this requirement**	**Term expiration** *Serve 3 year terms with 1 year between terms except for ACOS or C/R&D and Ex-Officio members*
ACOS/R&D or C/R&D functions as the Executive Secretary and has 1 vote		
Medical Center Director, Chief of Staff, and Administrative Officer or Administrative Assistant to R&D serve as Ex-Officio members with no vote		

1-3 members from the affiliated institution as representatives of the Dean's Committee. Can have up to 4 members if more than one affiliate is represented (Note: this requirement does not apply to non-affiliated VA Medical Centers)		
2-4 members from the VA staff - employees with or without compensation who have a major commitment of their professional time to patient care or management responsibilities, preferably with experience in research		
1-3 VA employees (with or without compensation who have a major commitment of their professional time to the VA) who are actively engaged in major R&D programs or can provide R&D expertise		
At least one member (from above) who is not a physician		
Additional membership to provide better oversight		
If possible, at least one member (from above) with expertise in biostatistics and research design		
If possible, at least one member (from above) with expertise in animal studies		

- ❑ Do you have a procedure at your facility for reviewing the activities of the **R&D Committee** to ensure that it is appropriately protecting and safeguarding human subjects research participants at your facility?

- ❑ Does your **IRB or Subcommittee on Human Studies** have at least 5 members, and do these members include representatives that meet the following criteria? (Note: Criteria from both regulations and NCQA Standard IRB 1A will be a "must pass" standard)

    - o *Must include persons with professional competence necessary to review specific research activities and persons able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law and standards of professional conduct and practice.*

    - o *Diversity of membership based on consideration of race, gender, cultural background, sensitivity to community attitudes, knowledge of applicable laws, standards, & regulations, and knowledge of vulnerable populations if they are included in proposed research. (Note: Veterans may be perceived as a vulnerable population)*

    - o *No member may participate in the IRBS initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.*

    - o *May invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.*

Member Name *(At least 5 members)*	**Scientific/ Non-scientific** *Must have at least 1 of each*	**Not affiliated with VA or Affiliate University & immediate family not affiliated with either**	**Profession** *Representing more than 1 profession*	**Chair with VA appt.** *Required if VA IRB*	**Member w/VA appt.** *Required if Affiliate IRB*	**R&D Committee Member** *Required if VA IRB*

- ❑ If you use your academic affiliate's IRB, is there at least one VA member present when VA protocols are reviewed?

4. Policies

Does your institution have written policies and procedures governing the following?
(38 CFR §16.103 & Federalwide Assurance of Protection of Human Subjects – OHRP, 3/20/2002)

- ❑ Conducting initial and continuing review of research at least once a year (and more often if risks warrant)

- ❑ Reporting findings to the investigator and the institution

- ❑ Determining which projects, based on degree of risk (not synonymous with "high risk") require more frequent review

- ❑ Determining which projects require outside verification that no material changes have occurred since the previous review

- ❑ Ensuring that changes in approved research protocols are reported promptly and not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject

- ❑ Ensuring prompt reporting to the IRB, appropriate institutional officials, OHRP, FDA when applicable, and ORO:
  -Any unanticipated problems involving risks to subjects or others
  -Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB
  -Any suspensions or termination of IRB approval

- ❑ Verifying whether proposed research activities qualify for expedited review or are exempt from review based on the Common Rule *(The person(s) who make this determination cannot be involved in the proposed research)*

- ❑ Expedited review procedures that include the requirement for minimal risk and conform to the list of categories of research that may be reviewed by the IRB through an expedited process. (38 CFR §16.110)

- ❑ Approving, requiring modifications, or disapproving human subjects research *(Note: these are the only 3 actions that an IRB should take, and they should be stated as such in the minutes)*

- ❑ Communicating significant new findings to subjects

- ❑ Criteria for approval of research include: (38 CFR §16.111)
  - o Risks to subjects are minimized
  - o Risks to subjects are reasonable in relation to anticipated benefits
  - o Selection of subjects is equitable
  - o Written informed consent will be obtained from each participant prior to the beginning of the research (this can be waived in some cases)
  - o When appropriate, provisions for monitoring the data collected to ensure the safety of subjects
  - o When appropriate, provisions to protect the privacy of subjects and maintain confidentiality of data
  - o Safeguards to protect vulnerable subjects

- ❑ Procedures for preparing and maintaining adequate IRB records to include: (38 CFR §16.115)
  - o Copies of all research proposals reviewed, scientific evaluations, sample consent documents, progress reports, and any reports of injuries to subjects
  - o Statements of significant new findings provided to subjects
  - o Minutes of IRB meetings include: (VHA Handbook 1200.5)
    - ▪ Attendance at meetings
    - ▪ Actions taken by the IRB
    - ▪ Vote on these actions including the number of members voting for, against, and abstaining
    - ▪ The basis for requiring changes in or disapproving research
    - ▪ Recusals and maintaining quorum
    - ▪ Risks and benefits
    - ▪ Waiver of consent or documentation of special protection for vulnerable subjects
    - ▪ A written summary of the discussion of controverted issues and their resolution
  - o Records of continuing review activities
  - o Copies of all correspondence between the IRB and the investigator
  - o Written procedures for the IRB
  - o A detailed list of IRB members
  - o Records shall be maintained for:
    - -3 years after consideration for disapproved proposals
    - -3 years after the conclusion of research for approved proposals
  - o Conflict of interest policy that addresses employment or other relationships with the institution for
    - -Full-time employees
    - -Part-time employees
    - -Members of governing panel or board
    - -Paid or unpaid consultants
  - o Documentation of required training and credentialing

- ❑ Do you have a training plan and review process to ensure that all staff involved in human research participant protection are appropriately trained?

- ❑ Do you have institutional policies, procedures, and plans that address the following
  - Reporting requirements:
    - Unanticipated problems involving risks to subjects or others
    - Serious or continuing noncompliance with the Federal Regulations or IRB requirements
    - Suspension or termination of IRB approval
  - Long-range planning to ensure continuation of research in the event of the absence of an investigator.
    - *This is of particular importance when research staff are called to active duty in times of war or national emergency, thus decreasing the number of staff available to conduct research*
  - Process to review or oversee informed consent process and documentation
  - Process to ensure that all staff (including WOC appointees) are appropriately credentialed and that they have been checked against exclusion lists.